



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/458,978	06/02/95	EDELMAN	E MIT6584

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18M2/0702

EXAMINER
NAFF, D

ART UNIT	PAPER NUMBER
1808	

DATE MAILED: 07/02/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4/9 + 4/30/97
☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-18 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) filed 4/30/97
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

Receipt is acknowledged of the amendment of 4/9/97 and the Information Disclosure Statement of 4/30/97.

References lined through on form PTO-1449 of the disclosure statement have not been considered since copies of the references have
5 not been supplied.

The amendment amended claims 1, 3, 6, 8, 11, 13, 16 and 18, and canceled claim 19.

Claims examined on the merits are 1-18 which are all claims in the case.

10 Claims 1-10 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

15 The specification fails to contain support for "without needing restoration of the endothelial cell lining of the blood vessel" (bridging lines 3 and 4 of claim 1) and for "compounds regulating the renin-angiotensin axis" in claims 8 and 18. The specification fails to disclose or support that injury to vascular tissue does not injure the
20 endothelial cell lining so as not to require restoration of the "endothelial cell lining. The specification also fails to disclose or support "compounds regulating the renin-angiotensin axis".

Claims 3, 6, 8 and 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out
25 and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 6, 13, 14 and 16 are confusing and unclear by the Markush groups of the claims containing members that are not mutually exclusive for reasons set forth in the previous office action of 1/16/97. Inserting "or" between members does not make them mutually exclusive. The broadest member should be selected and the other deleted. The ones deleted may be claimed in separate dependent claims.

In claim 14, any of the cells can be genetically engineered cells. It is suggested that genetically engineered cells be claimed in a separate dependent claim.

In claims 8 and 18, the meaning and scope of "compounds regulating the renin-angiotensin axis" is uncertain. This limitation is not recited and defined in the specification. Additionally, in the last line of these claims, to be clearer, -- factors -- should be inserted after "angiogenic", first occurrence, and in claim 8 the first occurrence of "and" in the last line should be replaced with a comma. Furthermore, in claims 8 and 18, it appears "anti-oxidants" and "free radical scavengers" can be the same. One of these should be in a separate dependent claim.

In claim 12, the difference in "coronary artery bypass surgery" and "peripheral bypass surgery" is uncertain. The dictionary pages supplied do not distinguish these two surgeries. They should be required in separate dependent claims unless they can be established to be mutually exclusive. Furthermore, "organ transplantation" is uncertain as to meaning and scope since parts of the body that are and are not an organ is unclear. It is suggested that organ be replaced with -- tissue --.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edelman et al ('928) or ('039) or ('532) in view of prior art disclosed in the specification (under "Background of the Invention" beginning on page 1, and paragraph bridging pages 2 and 3) and Yannas ('900) and Vacanti et al ('612), and if necessary in further view of Barrera et al ('665) or Yannas et al ('691) for reasons set forth in the previous office action of 1/16/97 in regard to claims 1-19.

Applicant's arguments filed 4/9/97 have been fully considered but they are not persuasive.

Applicants urge that the rejection cannot be responded to for failure to identify which of the numerous prior art publications the examiner is relying on for what purpose. However, the examiner has clearly identified each prior art reference and its purpose. This is apparent from the rejection which stated "It would have been obvious to incorporate endothelial cells in combination with the modulator such as an angiogenic factor in the polymer matrix of Edelman et al for repairing injured blood vessels to replace endothelial cells removed by injury to obtain the function of the cells that is known in the prior art as disclosed in the specification, i.e. the function to produce inhibitors of smooth muscle cell proliferation that results from endothelial cell removal by blood vessel injury. The disclosure by Yannas of incorporating endothelial cells in a blood vessel prothesis to generate endothelial cells for blood vessel repair *in vivo* and by Vacanti et al (col 5, lines 5-10) of incorporating both cells and an angiogenic compound in a matrix for implanting to generate and repair

tissue *in vivo* would have suggested that endothelial cells will function in combination with the modulator in the matrix of Edelman et al to replace endothelial cells removed from a blood vessel by injury. The disclosures of Barrera et al and Yannas et al of also implanting
5 matrices containing endothelial cells to generate and repair tissue, if needed, would have further suggested providing endothelial cells in the matrix of Edelman et al to replace endothelial cells removed by injury to a blood vessel".

The Barrera et al and Yannas et al ('691) references are combined
10 with other references and these references not disclosing all aspects of the invention does not make the rejection untenable. The invention becomes obvious when all the references are considered together as a whole.

It is clear from Edelman et al that compounds that inhibit
15 restenosis can be put in a matrix and the matrix provided near an injury to a blood vessel. In regard to known prior art, the specification discloses that endothelial cells produce compounds that inhibit undesirable proliferation of smooth muscle cells after an injury that causes removal of endothelial cells. Thus, it would have
20 been clearly obvious to provide endothelial cells in the matrix of Edelman et al to produce the compounds that inhibit restenosis and proliferation of smooth muscle cells.

Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-
ms 1-10 or claims 1-24 of U.S. Patent No. 5,540,928, 5,455,039
7,532, respectively, in view of prior art disclosed in the

specification (under "Background of the Invention" beginning on page 1) and Yannas ('900) and Vacanti et al ('612), and if necessary in further view of Barrera et al ('665) or Yannas et al ('691) for the type of reasons set forth in the rejection under 103 supra over the references.

5 This rejection has not been traversed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10 A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened
15 statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

25 If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

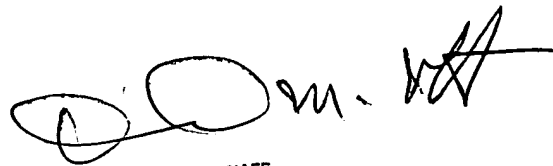
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The fax phone number is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1808

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DMN
6/26/97